

REMARKS

Reconsideration of the rejections set forth in the Office Action dated December 29, 2006 is respectfully requested.

Interview Summary

A telephonic interview between Applicants' representatives Joanne R. Petithory and Norman J. Kruse of Maxygen, Inc., Examiner Jegatheesan Seharaseyon, and Examiner Christine J. Saoud was conducted on May 22, 2007. In this interview proposed claim amendments to overcome the 35 U.S.C. § 112 second paragraph rejections were discussed, along with the provisional obviousness-type double patenting rejections. The previous restriction of SEQ ID NO:12 and SEQ ID NO:10 was also discussed. In view of the fact that SEQ ID NO:12 and SEQ ID NO:10 differ by only a single amino acid, Examiners Seharaseyon and Saoud agreed to withdraw the restriction requirement between SEQ ID NO:12 and SEQ ID NO:10, and permit Applicants to pursue claims directed to variants of SEQ ID NO:10 as well as SEQ ID NO:12 in the instant application. Examiners Seharaseyon and Saoud also agreed to withdraw the provisional obviousness-type double patenting rejections and consider them in later-filed applications, where appropriate.

Applicants thank Examiner Seharaseyon and Examiner Saoud for the highly informative and productive interview.

Status of and Amendments to the Claims

Claim 1 is amended herein to incorporate the limitations of claim 5, and claim 5 is canceled herein. Claims 1, 8, 10, and 32 are amended to clarify the activity limitations of these claims. Claims 10, 21, 22 and 32 are amended herein to independent form by incorporating limitations of the claims from which they previously depended. New claims 46-73 drawn to restriction Group I and SEQ ID NO:10 are added herein, pursuant to the telephonic interview summarized above.

The claim amendments and the new claims add no new matter to the application. Claims 1, 6-22, 32, 37-45, and 46-73 are pending with entry of this amendment, with claims 19-20 and new claims 60-61 currently withdrawn as being drawn to a non-elected species.

Group II claims 23-31 and 33-34, Group III claims 35-36, Group I claims 2-3 (drawn to a non-elected sequence), and Group I claim 4 (the limitations of which were redundant to claim 1 as amended therein) were canceled without prejudice by way of the Preliminary Amendment and Response to Restriction filed October 16, 2006.

Information Disclosure Statements

Applicants note with appreciation the Examiner's consideration of the references cited in the Information Disclosure Statements submitted on October 6, 2006, October 27, 2006, November 8, 2006 and November 14, 2006, as evidenced by the initialed and signed copies of the relevant forms SB-08 included with the December 29, 2006 Office Action.

Rejections under 35 U.S.C. 112, Second Paragraph

Claims 1, 5-22, 32 and 37-45 were rejected under 35 U.S.C. §112, second paragraph, for indefiniteness. Applicants respectfully request reconsideration and withdrawal of this rejection in view of the following amendment and remarks.

A. Claims 1, 10 and 32:

Claims 1, 10 and 32 (and claims 5-9, 11-22, and 37-45 which depend from claim 1, 10, or 32) were rejected as vague and indefinite for reciting the term "an antiviral activity". The rejection of claim 5 is moot in view of the cancellation of that claim.

Claims 1, 10, and 32 have been amended, as suggested by the Examiners in the telephonic interview, to recite the phrase "exhibits antiviral activity". It is noted that claims 21 and 22 have been amended herein to independent form by incorporating the limitations of claims 1 and 10, respectively, so now claims 21 and 22 also include this limitation.

In view of these claim amendments, Applicants respectfully request that the rejection of claims 1, 10 and 32, and pending claims 6-9, 11-20, and 37-45 which depend from claim 1, 10, or 32, and newly-amended pending claims 21 and 22, under 35 U.S.C. §112 (second paragraph) be withdrawn.

B. Claim 8:

Claim 8 (and claim 9 which depends from claim 8) was further rejected as vague and indefinite for reciting the term “an interferon-alpha antiproliferative activity”.

Claim 8 been amended, as suggested by the Examiners in the telephonic interview, to recite the phrase “exhibits antiproliferative activity”.

In view of the claim amendment, Applicants respectfully request that the rejection of claim 8, and claim 9 which depends from claim 8, under 35 U.S.C. §112 Second Paragraph be withdrawn.

Rejections under 35 U.S.C. §112, First Paragraph

A. Written Description:

Claims 1, 6-22, 32 and 37-45 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in a way that reasonably conveys to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. It is noted that claim 5 was not included in this rejection. Applicants respectfully request reconsideration and withdrawal of this rejection in view of the following amendment and remarks.

Claim 1 has been amended herein to incorporate the limitations of claim 5, which was not rejected under 35 U.S.C. §112, First Paragraph (Written Description). Claim 10, which has been amended herein to independent form to incorporate the limitations of amended claim 1 (and therefore the limitations of claim 5 as well), should likewise be free of the rejection. Claims 21 and 32, which have been amended herein to independent form to incorporate the limitations of amended

claim 1, and claim 22, which has been amended herein to independent form to incorporate the limitations of amended claim 10, should likewise be free of the rejection. Applicants respectfully submit that the rejection of claim 1, the rejection of claims 10, 21, 22, and 32 which previously depended from claim 1 or claim 10 and now incorporate the limitations of claim 1 or claim 10 in independent form, and the rejection of claims 6-9, 11-20, and 37-45 which depend from claim 1, 10, or 32, have been overcome by this amendment. Withdrawal of the rejection of these claims under 35 U.S.C. §112, First Paragraph (Written Description) is respectfully requested.

B. Enablement:

Claims 1, 6-22, 32 and 37-45 were rejected under 35 U.S.C. §112, first paragraph, because the disclosure allegedly does not provide reasonable enablement for the claimed interferon-alpha variants. It is noted that claim 5 was not included in this rejection. Applicants respectfully request reconsideration and withdrawal of this rejection in view of the following amendment and remarks.

Claim 1 has been amended herein to incorporate the limitations of claim 5, which was not rejected under 35 U.S.C. §112, First Paragraph (Enablement). Claim 10, which has been amended herein to independent form to incorporate the limitations of amended claim 1 (and therefore the limitations of claim 5 as well), should likewise be free of the rejection. Claims 21 and 32, which have been amended herein to independent form to incorporate the limitations of amended claim 1, and claim 22, which has been amended herein to independent form to incorporate the limitations of amended claim 10, should likewise be free of the rejection. Applicants respectfully submit that the rejection of claim 1, the rejection of claims 10, 21, 22, and 32 which previously depended from claim 1 or claim 10 and now incorporate the limitations of claim 1 or claim 10 in independent form, and the rejection of claims 6-9, 11-20, and 37-45 which depend from claim 1, 10, or 32, have been overcome by this amendment. Withdrawal of the rejection of these claims under 35 U.S.C. §112, First Paragraph (Enablement) is respectfully requested.

Provisional Nonstatutory Obviousness-Type Double Patenting Rejections

Various pending claims in the instant application were provisionally rejected on the grounds of Nonstatutory Obviousness-Type Double Patenting as being unpatentable over certain claims in copending applications filed by the Applicants. These rejections will be addressed in more detail below.

A. - E. Provisional Rejections over Divisional Applications

As an initial matter, copending applications used as references against the instant application in the Nonstatutory Obviousness-Type Double Patenting rejections numbered A. through E. in the Office Action dated December 26, 2006 are divisionals of the instant application, filed as a direct result of the Requirement for Restriction/Election dated October 11, 2006 in the instant application, as summarized below.

In the Requirement for Restriction/Election dated October 11, 2006 in the instant application, original claims 1-36 were restricted under 35 U.S.C. §121 into the following three groups:

- I. Claims 1-22 and 32, drawn to isolated polypeptide, classified in class 530, subclass 350.
- II. Claims 23-31 and 33-34, drawn to a DNA sequence comprising a nucleotide sequence encoding a polypeptide, a vector and host cell, classified in class 536, subclass 23.5.
- III. Claims 35-36, drawn to a method for inhibiting replication of a virus in cells infected with the virus, classified in class 424, subclass 85.4.

The recited sequences were furthermore subject to restriction under 35 U.S.C. §121, and Applicants were instructed to elect a single sequence for examination.

The Examiner further maintained that conjugate claim 10 and claims depending therefrom were drawn to patentably distinct species of non-polypeptide moiety covalently attached to an

attachment group of the polypeptide, specifically, a glycol and a sugar. Applicants assumed at the time they responded to the Restriction Requirement that the Examiner meant “polymer” rather than “glycol”, and proceeded on that assumption (*the Examiner affirmed this in the most recent Office Action, on p. 2, lines 4-6*). For claim 10, Applicants were required under 35 USC § 121 to elect a single disclosed species for prosecution on the merits, to which the claims shall be restricted if the generic claim(s) are not held to be allowable.

In the Preliminary Amendment and Response to Restriction filed October 16, 2006 in the instant application, Applicants elected Group I claims 1-22 and 32, and SEQ ID NO:12, and further elect the species of glycol (polymer) conjugates, for prosecution in the instant application, without traverse. Also, in the above-noted Preliminary Amendment filed October 16, 2006, Group II claims 23-31 and 33-34, Group III claims 35-36, and Group I claims 2-3 (drawn to non-elected SEQ ID NO:3), were canceled, without prejudice to filing in one or more continuation and/or divisional applications.

As a result of the Restriction Requirement dated October 11, 2006 and the Preliminary Amendment and Response to Restriction filed October 16, 2006, the following Divisional applications were filed:

USSN 11/554,328 filed October 30, 2006 (Attorney Docket No 0269us411). A Preliminary Amendment was submitted together with the application, in which Group II claims 23-31 and 33-34 and SEQ ID NO:12 were elected for prosecution in the application without traverse, the claims were amended in accordance with this election, and claims 1-22 and 32, and claims 35-36, drawn to non-elected restriction groups, were canceled.

USSN 11/554,377 filed October 30, 2006 (Attorney Docket No 0269us412). A Preliminary Amendment was submitted together with the application, in which Group III claims 35-36, SEQ ID NO:12, and the species of glycol (polymer) conjugates were elected for prosecution in the application without traverse, the claims were amended in accordance with this election, and claims 1-22 and 32, and claims 23-31 and 33-34, drawn to non-elected restriction groups, were canceled.

USSN 11/554,487 filed October 30, 2006 (Attorney Docket No 0269us413). A Preliminary Amendment was submitted together with the application, in which Group I claims 1-22 and 32, SEQ ID NO:10 and the species of glycol (polymer) conjugates were elected for prosecution in the application without traverse, and the claims were amended in accordance with this election. Claims 23-31 and 33-34, and claims 35-36, drawn to non-elected restriction groups, and Group I claims 2-3 drawn to non-elected sequences, were canceled.

USSN 11/554,507 filed October 30, 2006 (Attorney Docket No 0269us414). A Preliminary Amendment was submitted together with the application, in which Group II claims 23-31 and 33-34, and SEQ ID NO:10 were elected for prosecution in the application without traverse, the claims were amended in accordance with this election, and claims 1-22 and 32, and claims 35-36, drawn to non-elected restriction groups, were canceled.

USSN 11/554,521 filed October 30, 2006 (Attorney Docket No 0269us415). A Preliminary Amendment was submitted together with the application, in which Group III claims 35-36, SEQ ID NO:10 and the species of glycol (polymer) conjugates were elected for prosecution in the application without traverse, the claims were amended in accordance with this election, and claims 1-22 and 32, and claims 23-31 and 33-34, drawn to non-elected restriction groups, were canceled.

USSN 11/554,547 filed October 30, 2006 (Attorney Docket No 0269us416). A Preliminary Amendment was submitted together with the application, in which Group I claims 1-22 and 32, SEQ ID NO:3 and the species of glycol (polymer) conjugates were elected for prosecution in the application without traverse, and the claims were amended in accordance with this election. Claims 23-31 and 33-34, and claims 35-36, drawn to non-elected restriction groups, and Group I claims 4-5 drawn to non-elected sequences, were canceled.

USSN 11/554,557 filed October 30, 2006 (Attorney Docket No 0269us417). A Preliminary Amendment was submitted together with the application, in which Group II claims 23-31 and 33-34 and SEQ ID NO:3 were elected for prosecution in the application without traverse, the claims were

amended in accordance with this election, and claims 1-22 and 32, and claims 35-36, drawn to non-elected restriction groups, were canceled.

USSN 11/554,565 filed October 30, 2006 (Attorney Docket No 0269us418). A Preliminary Amendment was submitted together with the application, in which Group III claims 35-36, SEQ ID NO:3 and further elect the species of glycol (polymer) conjugates were elected for prosecution in the application without traverse, the claims were amended in accordance with this election, and claims 1-22 and 32, and claims 23-31 and 33-34, drawn to non-elected restriction groups, were canceled.

According to 35 U.S.C. §121:

A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

35 U.S.C. §121 thus provides that neither a divisional application filed as a result of a Restriction Requirement, nor the application in which the Restriction Requirement was made, nor any patent issuing from either of these applications, can be used as a reference in a Double Patenting rejection against the other.

In the Office Action dated December 29, 2006, the following divisional application were cited in provisional Nonstatutory Obviousness-Type Double Patenting rejections against the instant application:

- A. USSN 11/554,487 (Attorney Docket No. 0269us413)
- B. USSN 11/554,507 (Attorney Docket No. 0269us414)
- C. USSN 11/554,521 (Attorney Docket No. 0269us415)

D. USSN 11/554,547 (Attorney Docket No. 0269us416)

E. USSN 11/554,565¹ (Attorney Docket No. 0269us418)

In view of 35 U.S.C. §121, Applicants respectfully submit that the provisional Nonstatutory Obviousness-Type Double Patenting rejections of pending claims in the instant application over claims pending in the divisional applications listed above are improper, and should be withdrawn.

Telephonic Interview:

In the telephonic interview on May 22, 2007, Examiners Seharaseyon and Saoud noted that, since the instant application was the first in this family to be filed and should be the first to issue as a patent, the outstanding Nonstatutory Obviousness-Type Double Patenting rejections of pending claims in the instant application over claims pending in the related divisional applications would be withdrawn, and any Nonstatutory Obviousness-Type Double Patenting issues which remain would be addressed in the later-filed divisional applications.

Furthermore, owing to the close similarity of SEQ ID NO:10 to SEQ ID NO:12 (one amino acid difference at position 47), Examiners Seharaseyon and Saoud agreed to examination of Group I claims in the instant application which are directed to polypeptides comprising a sequence which differs in 0 to 8 amino acid positions from the sequence of SEQ ID NO:10, conjugates thereof and methods of making such conjugates, in addition to the pending claims directed to the previously-elected SEQ ID NO:12.

Applicants furthermore request that, in USSN 11/554,328 filed October 30, 2006 (Attorney Docket No 0269us411), in which Group II claim drawn to nucleic acids encoding SEQ ID NO:12 and variants thereof are currently pending, the Examiner will also examine claims drawn to nucleic acids encoding SEQ ID NO:10 and variants thereof.

¹ The rejection set forth in Section 6e on page 13 of the Office Action referred to "copending Application No. 11/554,507 ('565)". Since a rejection over the '507 application was made in Section 6b. on page 11 of the Office Action, Applicants will proceed on the assumption that the rejection in Section 6e is in fact over Applicants' copending application 11/554,565.

Applicants likewise request that, in USSN 11/554,377 filed October 30, 2006 (Attorney Docket No 0269us412), in which Group III claims drawn to methods employing SEQ ID NO:12 and variants and conjugates thereof are currently pending, the Examiner will also examine claims drawn to methods employing SEQ ID NO:10 and variants and conjugates thereof.

The Examiner is requested to confirm the withdrawal of the requirement for restriction between SEQ ID NO:12 and SEQ ID NO:10 in the next written action from the Office.

F. Provisional Rejection over USSN 10/714,817 (Attorney Docket No. 0269us310)

Claims 1, 5-22, 32 and 37-45 were provisionally rejected on the grounds of Nonstatutory Obviousness-Type Double Patenting as being allegedly unpatentable over claims 1-2, 4, 6-18, 21-22 and 32 of copending application USSN 10/714,817 ("the '817 application").

The '817 application went abandoned effective April 9, 2007, so this rejection is moot.

G. - J. Provisional Rejections over Later-Filed Applications

In the Office Action dated December 29, 2006, the following pending applications, each of which having an effective filing date of May 18, 2005, were cited in provisional Nonstatutory Obviousness-Type Double Patenting rejections against the instant application:

- G. USSN 11/532,045² (Attorney Docket No. 0280.360US)
- H. USSN 11/532,024³ (Attorney Docket No. 0280.350US)
- I. USSN 11/569,345 (Attorney Docket No. 0269.510US)
- J. USSN 11/132,722 (Attorney Docket No. 0280.310US)

² The application serial number was identified as 11/352,045 in the Office Action, however, the correct serial number of Applicants' copending application is 11/532,045.

³ The application serial number was identified as 11/352,024 in the Office Action, however, the correct serial number of Applicants' copending application is 11/532,024.

Applicants respectfully request that the provisional rejections over the later-filed applications listed above be held in abeyance until all other patentability issues in the instant application are resolved. If these provisional rejections are the only rejections remaining in the instant application, Applicants request that the Examiner withdraw these rejections and allow the instant application to issue as a patent without a Terminal Disclaimer, pursuant to MPEP § 804 I.B.1.

Telephonic Interview:

In the telephonic interview on May 22, 2007, Examiners Seharaseyon and Saoud noted that, since the instant application was filed earlier than the above-noted applications, and should be the first to issue as a patent, the outstanding Nonstatutory Obviousness-Type Double Patenting rejections of pending claims in the instant application over claims pending in the above-noted later filed applications would be withdrawn, and any Nonstatutory Obviousness-Type Double Patenting issues which remain would be addressed in the later-filed applications.

Additional Later-Filed Applications:

Applicants wish to inform the Examiner of the following additional later-filed applications, which are all either Divisionals or Continuations of USSN 11/132,722 noted above (item J.) filed May 18, 2005, and thus have effective filing dates of May 18, 2005:

USSN 11/531,531 filed September 13, 2006 (Attorney Docket No. 0280.320US)
USSN 11/531,557 filed September 13, 2006 (Attorney Docket No. 0280.330US)
USSN 11/531,570 filed September 13, 2006 (Attorney Docket No. 0280.340US)
USSN 11/569,266 filed November 17, 2006 (Attorney Docket No. 0280.31W US)
USSN 11/744,424 filed May 4, 2007 (Attorney Docket No. 0280.311US)

CONCLUSION

This amendment cancels 1 dependent claim, amends four dependent claims to independent form, and adds 28 new claims, five of which are independent. The Commissioner is hereby authorized to charge \$3200 (\$1350 for 27 additional claims and \$1400 for 7 independent claims in excess of those already paid for, plus \$450 for the Two-Month Extension of Time) to Deposit Account No. 50-0990. Please charge any additional fees which may be due, or credit any overpayment, to Deposit Account No. 50-0990.

In view of the amendments and remarks provided above, it is believed that the pending claims are in condition for allowance, and notification to that effect is respectfully requested. Should the Examiner feel that there are any issues outstanding after consideration of this paper, the Examiner is invited to telephone the undersigned at (650) 298-5452.

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Respectfully submitted,



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